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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,670	07/24/2000	Mark Ashby	032005-068	6902
7590	04/07/2006		EXAMINER	
Robert E. Kerbs Burns, Doane, Swecker & Mathis L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			IZAGUIRRE, ISMAEL	
			ART UNIT	PAPER NUMBER
			3765	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/621,670	ASHBY ET AL.
	Examiner Ismael Izaguirre	Art Unit 3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 September 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-42 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-36 and 44 is/are allowed.
- 6) Claim(s) 37-41 and 45 is/are rejected.
- 7) Claim(s) 42 and 46-48 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

The examiner is appreciative of the changes made to the language of the claims.

These have been duly noted and considered.

### **CLAIMS**

#### **Summary**

Claims 1,14,25,38,44 and 48 are the independent claims under consideration in this Office action.

Claims 2-13,15-24,26-37,39-42 and 46-48 are the dependent claims under consideration in this Office action.

Concerning the language of the claims, the following is submitted for applicant's consideration:

#### **Claim Rejections - 35 U.S.C. § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to this claim, the dependency is unclear. It should be corrected to depend from a preceding claim.

Concerning the patentability of the claims, the following Double patenting rejection, and newly applied (Nash et al.) and newly found art (Van Tassel et al.) rejections are submitted for applicant's consideration:

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 45 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 66 of copending Application No. 09/613,439. Although the conflicting claims are not identical, they are not patentably distinct from each other because '439 claims a method for facilitating homeostasis of a puncture at an exterior surface of a blood vessel. '439 claims that the pusher is held stationary relative to the introducer (delivery cannula) and then withdrawing the introducer (delivery cannula) to expose the distal end of the pledget. Appling a forward

pressure on the pusher and the pledget it exposed and compressed against the exterior surface of the blood vessel puncture.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Claim Rejections - 35 U.S.C. § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38, 39 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable Nash et al. (6,090,130) in view of Brenneman et al. (5,645,566).

Nash et al. discloses the invention substantially as claimed. Nash et al. teach a method of measuring the distance between an epidermal outer surface and the outer surface of a blood vessel having a puncture therethrough at a puncture site. Nash et al. teach advancing a control tip 34 through tissue and into the blood vessel through the puncture. A tubular shaft 28 is advanced over the control tip until the distal end of the tubular shaft engages the outer surface of the blood vessel and blood flashes out a proximal end of the tubular shaft (column 9, last paragraph). Nash et al. teach a marker 150 for measuring at what depth the vessel is and the distance from the outer surface of the patient to the outer surface of the vessel. However, Nash et al. do not

suggest the marker as being placed over the shaft at the epidermal outer surface of the patient.

Brenneman et al. teach a sealing apparatus for sealing a puncture in a blood vessel. Brenneman et al. teach a shaft 12 for accommodating a control tip 30, 20 and 42, which are movable within the cannula of the shaft 12. When the proper positioning of the control tip is acquired, then a distance from the outer surface of the blood vessel to the epidermal surface of the patient is marked by providing a marker 60. The marker is placed around the shaft at the epidermal surface of the patient.

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the marker of Nash et al. as including a marker placed at the epidermal surface of the patient. Providing this would allow the positive location and retention of the tubular shaft relative to the outer epidermal surface of the patient assuring a proper measuring of the distance between the outer surface of the blood vessel to the epidermal surface.

Claims 38 and 40 are rejected under 35 U.S.C. § 103(a) as being unpatentable Van Tassel et al. (5,292,309) in view of Brenneman et al. (5,645,566).

Van Tassel et al. disclose the invention substantially as claimed. Van Tassel et al. teach a method of measuring the distance between an epidermal outer surface and the outer surface of a blood vessel having a puncture therethrough at a puncture site. Nash et al. teach advancing a control tip 30 through tissue and into the blood vessel through the puncture. A tubular shaft 18 is advanced over the control tip and then is stopped until blood flashes through the distal end 32 of the tubular shaft and out a

proximal end of the tubular shaft. Van Tassel et al. teach a markings along the shaft (figure 6, for example) for measuring at what depth the vessel is and the distance from the outer surface of the patient to the outer surface of the vessel. However, Van Tassel et al. do not suggest a marker as being placed over the shaft at the epidermal outer surface of the patient.

Brenneman et al. teach a sealing apparatus for sealing a puncture in a blood vessel. Brenneman et al. teach a shaft 12 for accommodating a control tip 30, 20 and 42, which are movable within the cannula of the shaft 12. When the proper positioning of the control tip is acquired, then a distance from the outer surface of the blood vessel to the epidermal surface of the patient is marked by providing a marker 60. The marker is placed around the shaft at the epidermal surface of the patient.

It would have been obvious to a person having ordinary skill in the art at the time of Applicant's invention to construct the device of Van Tassel et al. as including a marker placed at the epidermal surface of the patient. Providing this would allow the positive location and retention of the tubular shaft relative to the outer epidermal surface of the patient assuring a proper measuring of the distance between the outer surface of the blood vessel to the epidermal surface.

#### **ALLOWABLE SUBJECT MATTER**

Claims 1-36 and 44 are allowable over the prior art of record.

Claims 37 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112.

Claims 42 and 46-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### INQUIRIES

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ismael Izaguirre whose telephone number is (571) 272-4987. The examiner can normally be reached on M-F (8:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (571) 272-4983. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ismael Izaguirre  
Primary Examiner  
Art Unit 3765